

K062684

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B. 510(k) SUMMARY (as required by 21 CFR 807.92)

NOV 22 2006

**Excia Total Hip System
(Excia 36mm Ceramic Head)
September 8, 2006**

COMPANY: Aesculap[®], Inc.
3773 Corporate Parkway
Center Valley, PA 18034
Establishment Registration Number: 2916714

CONTACT: Kathy A. Racosky
800-258-1946 (phone)
610-791-6882 (fax)
kathy.racosky@aesculap.com (email)

TRADE NAME: Excia Total Hip System 36mm Ceramic Head

COMMON NAME: Ceramic Ball Head

CLASSIFICATION NAME: Prosthesis, hip, semi-constrained,
metal/ceramic/polymer, cemented or non-porous
uncemented prosthesis
Prosthesis, hip, semi-constrained, uncemented,
metal/polymer, non-porous, calcium-phosphate
Prosthesis, hip, semi-constrained, metal/polymer,
uncemented
Prosthesis, hip, semi-constrained, metal/polymer,
cemented

REGULATION NUMBER: 888.3353, 888.3353, 888.3360, 888.3350

PRODUCT CODE: LZO, MEH, LWJ, JDI

SUBSTANTIAL EQUIVALENCE

Aesculap[®], Inc. believes that the 36mm Ceramic Head is a line extension of Aesculap's Excia Total Hip System that was cleared (K042344). It is also substantially equivalent to the Excia Total Hip System 12/14 Trunnion with Ceramic Head (K060918).

DEVICE DESCRIPTION

The Excia 36mm Ceramic Head is manufactured from ceramic (Al₂O₃) and conforms to ISO 6474. The 36mm diameter head is offered in three different head lengths (-3.5 mm, 0 mm, and +3.5mm). These ceramic heads allow the surgeon further option to meet the patient's needs.

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INDICATIONS FOR USE

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur.
- Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
- Patients suffering from disability due previous fusion
- Patients with acute femoral neck fractures

The Excia Hip System is available with two femoral stems. One is manufactured from CoCrMo and is intended for cemented fixation. The other femoral stem is for uncemented fixation and manufactured from Ti with Plasmapore with or without μ CaP®.

TECHNOLOGICAL CHARACTERISTICS(compared to Predicate(s))

The new 36mm ceramic head of the Excia Total Hip System are offered in similar shapes and sizes as the predicate devices. The material used for the Aseculap device is the same as that used to manufacture the predicate devices.

PERFORMANCE DATA

All required testing per "Draft Guidance for the Preparation of Premarket Notifications (510(k)s) Applications for Orthopedic Devices-The Basic Elements" were done where applicable. In addition, testing per the;

- "Guidance Document for Testing Orthopedic Implants with Modified Metallic Surfaces Apposing Bone or Bone Cement",
- "Guidance for Industry on the Testing of Metallic Plasma Sprayed Coatings on Orthopedic Implants to Support Reconsideration of Postmarket Surveillance Requirements",
- "Guidance Document for Testing Non-articulating, "Mechanically Locked" Modular Implant Components",
- "Draft Guidance Document for Testing Acetabular Cup Prostheses",
- "Points to Consider for Femoral Stem Prostheses",
- "Guidance Document for the Preparation of Premarket Notifications for Ceramic Ball Hip Systems" and
- "Data Requirements for Ultrahigh Molecular Weight Polyethylene (UHMWPE) Used in Orthopedic Devices" was completed where applicable.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Aesculap, Inc.
% Ms. Kathy A. Racosky
Regulatory Affairs Associate
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

NOV 22 2006

Re: K062684

Trade/Device Name: Excia Total Hip System 36mm Ceramic Head
Regulation Number: 21 CFR 888.3353
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or
nonporous uncemented prosthesis
Regulatory Class: Class II
Product Code: LZO, JDI, LWJ, MEH
Dated: November 14, 2006
Received: November 15, 2006

Dear Ms. Racosky:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must

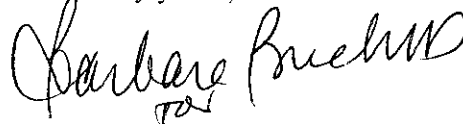
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comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/industry/support/index.html>.

Sincerely yours,

A handwritten signature in black ink, appearing to read "Mark N. Melkerson", with a stylized flourish at the end.

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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A. INDICATIONS FOR USE STATEMENT510(k) Number: K062684Device Name: **Excia 36mm Ceramic Head****Indications for Use:**

The Excia Hip System is intended to replace a hip joint.

The device is intended for:

- Patients suffering from severe hip pain and disability due to rheumatoid arthritis, osteoarthritis, traumatic arthritis, polyarthritis, collagen disorders, avascular necrosis of the femoral head and nonunion of previous fractures of the femur
- Patients with congenital hip dysplasia, protrusion acetabuli, or slipped capital femoral epiphysis
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Prescription Use X and/or Over-the-Counter Use _____
(per 21 CFR 801.109)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Barbara Buehler
(Division Sign-Off) *for MCM* Concurrency of GDRH, Office of Device Evaluation (ODE)

**Division of General, Restorative,
and Neurological Devices**

510(k) Number K062684